M360051

DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

# WARNING LETTER

March 30, 2000

REF: NYK-2000-55

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Clifford Beinart, M.D., Medical Director
Women's Outreach Network, Inc.
54 Lincoln Avenue
Islip Terrace, New York 11752

Facility ID: 167593
221521

Dear Dr. Beinart:

Your mobile facilities, Van 1 and Van 4, were inspected on March 7, 2000, by a representative of the Suffolk County Department of Health Services, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facilities.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facilities:

> ***Phantom QC records were missing for 6 weeks for Van 1. Weekly phantom films were not logged for May and June 1999.***
>
> ***Phantom QC records were missing for 7 weeks for Van 4. Weekly phantom films were not logged for May and June 1999.***
>
> ***The system to communicate results for Vans 1 and 4 is not adequate. There is no system in place to communicate serious or highly suggestive cases as soon as possible.***

The specific problems noted above appeared on your MQSA Facility Inspection Reports which were issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify failures to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, they represent violations of the law

which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

There were also Level 2 findings that were listed on the inspection reports provided at the close of the inspection. The Level 2 findings were:

> ***A performance verification test was not conducted after each move during May and June 1999 for Vans 1 and 4.***
>
> ***The phantom image score (using an FDA approved mammography phantom) is at least 3 fibers but less than 4 fibers for Van 4.***

We have received the response dated March 20, 2000 concerning these noncompliances submitted by Mary Solomon, Executive Director, of your facility. The response is generally satisfactory. She does, however, acknowledge in her item 5 that the person performing the QA tests is not a certified mammography technician. She concludes stating the QA person, an engineer, will become certified. Please respond as to whether or not this person plans to become registered and licensed as a x-ray technologist to fulfill the requirements as a certified mammography technician.

Please submit your response to the above issue to this office in writing within fifteen (15) working days from the day you received this letter. Your response should be sent to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,

Brenda J. Holman
District Director